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July 13, 2004

via Hand Delivery

Michael Kunz, Clerk
United States District Court
for the Eastern District of Pennsylvania
601 Market Street, Room 2609
Philadelphia, PA 19106

Re : Biovail Laboratories, Inc. v.
TorPharm, Inc.
Sub: Civil Action No. 02-CV-7119

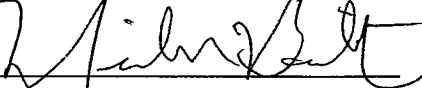
Dear Mr. Kunz:

Enclosed for filing is TorPharm's Motion for Leave to File a Second Amended Answer, Affirmative Defenses and Counterclaims, Memorandum of Law in Support Thereof including Exhibits A through G, and a proposed Order.

A copy is also enclosed on computer disk in PDF format.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW LTD.

By 
Michael J. Berkowitz

MJB:jw
enc

cc + 2 encs via Federal Express to:
Hon. Anita B. Brody
Room 7613

cc with enc. via 1st Class Mail to:
Eric Cohen, Esq. and Charles R. Krikorian, Esq.
cc with enc. via Hand Delivery to:
Robert S. Tintner, Esq.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

BIOVAIL LABORATORIES, INC.
a Corporation of Barbados

Plaintiff,

V.

TORPHARM, INC.
a Canadian Corporation

Defendant.

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Civil No. 02-7119

Judge Anita B. Brody

ORDER

AND NOW, this _____ day of _____, 2004, upon consideration of Defendant, TorPharm, Inc.'s Motion for Leave to File a Second Amended Answer, Affirmative Defenses and Counterclaims and Memorandum of Law in support thereof and Plaintiff, Biovail's opposition thereto, **IT IS HEREBY ORDERED** that Defendant's motion is **GRANTED**. TorPharm shall file its Second Amended Answer, Affirmative Defenses and Counterclaims within ten days of entry of this Order.

Honorable Anita B. Brody,
United States District Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

BIOVAIL LABORATORIES, INC.
a Corporation of Barbados

Plaintiff,

V.

TORPHARM, INC.
a Canadian Corporation

Defendant.

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Civil No. 02-7119

Judge Anita B. Brody

**TORPHARM, INC.'S MOTION FOR LEAVE TO FILE A SECOND AMENDED
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Pursuant to Rule 15 of the Federal Rules of Civil Procedure, defendant, TorPharm, Inc. (hereinafter “TorPharm”) hereby moves this court for leave to file a Second Amended Answer, Affirmative Defenses and Counterclaims (hereinafter "Second Amended Answer"). A copy of TorPharm’s proposed Second Amended Answer is attached hereto as Exhibit A. The language TorPharm proposes to add to this pleading is indicated in bold type.

For the reasons set forth in the Memorandum of Law included herewith, TorPharm respectfully requests that this Court grant its Motion For Leave for to File a Second Amended Answer, and enter the Proposed Order included herewith.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

July 13, 2004

By 

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CERTIFICATE OF SERVICE

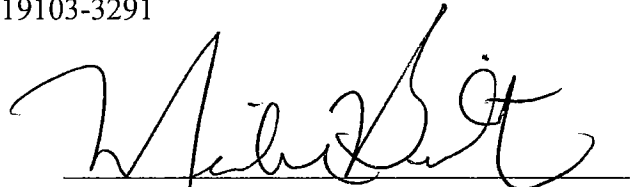
I hereby certify that one (1) true and correct copy of the foregoing **MOTION FOR LEAVE TO FILE A SECOND AMENDED ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS, MEMORANDUM OF LAW IN SUPPORT THEREOF** including Exhibits A through G, and **PROPOSED ORDER**, is being served upon counsel for Biovail Laboratories, Inc. via UNITED STATES MAIL, POSTAGE PREPAID in an envelope addressed to:

Eric C. Cohen
Robert B. Breisblatt
Charles R. Krikorian
WELSH & KATZ, LTD.
120 South Riverside Plaza - 22nd Floor
Chicago, Illinois 60606

and by hand delivery to the following local counsel:

Robert S. Tintner, Esq.
Fox, Rothschild, O'Brien & Frankel, LLP
2000 Market Street, Tenth Floor
Philadelphia, PA 19103-3291

on this 13 day of July, 2004.



Michael J. Berkowitz

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

BIOVAIL LABORATORIES, INC. a Corporation of Barbados	:	Civil No. 02-7119
	:	
Plaintiff,	:	Judge Anita B. Brody
	:	
	:	
v.	:	
	:	
TORPHARM, INC. a Canadian Corporation	:	
	:	
Defendant.	:	

**MEMORANDUM OF LAW IN SUPPORT OF
TORPHARM, INC.'S MOTION FOR LEAVE TO FILE A SECOND AMENDED
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Pursuant to Rule 15 of the Federal Rules of Civil Procedure, defendant, TorPharm, Inc. (hereinafter "TorPharm") hereby moves this court for leave to file a Second Amended Answer, Affirmative Defenses and Counterclaims (hereinafter "Second Amended Answer") to include additional counterclaims and affirmative defenses of invalidity based on claim overbreadth and antitrust violations for sham litigation under 15 U.S.C. § 2. This Motion should be granted because, in light of Biovail's recent clarification of its definition of the term "sugar," TorPharm is faced with new, viable defenses which should be included in the instant case. A copy of TorPharm's proposed Second Amended Answer is attached hereto as Exhibit A. The language TorPharm proposes to add to this pleading is indicated in bold type.

A. Facts

TorPharm filed Abbreviated New Drug Application (“ANDA”) No. 76-395 (“TorPharm's ANDA”) with the United States Food and Drug Administration (“FDA”) to market its generic version of the heart medication diltiazem hydrochloride. Plaintiff, Biovail Laboratories, Inc., (“Biovail”) subsequently sued TorPharm alleging infringement of United States Patent Nos. 5,529,791 (Exhibit B, “the '791 patent”) and 5,288,505 (Exhibit C, “the '505 patent”). Hereinafter, these two patents will collectively be referred to as “the patents-in-suit.”

1. The patents-in-suit and the definition of “sugar” and “sugars”

The patents-in-suit disclose a specific formulation of diltiazem, a drug that is used to treat angina and hypertension. Diltiazem or a salt of diltiazem - such as diltiazem hydrochloride - is the active ingredient in the formulation of the claims of the patents-in-suit. The claims of the patents-in-suit require the diltiazem or diltiazem salt to be in an admixture with a “wetting agent.” The definition of what constitutes a “wetting agent” as the term appears in the claims of the patents-in-suit is one of the disputed issues in this litigation.

The claims of the patents-in-suit require the “wetting agent” to be selected from a group of compounds including a “sugar” or “sugars.”

The specifications of the patents-in-suit give several examples of “sugars” that could be employed as “wetting agents.” The '791 patent lists saccharose, mannitol and sorbitol (see Exhibit B, the '791 patent, column 3, lines 14-17), while the '505 patent lists saccharose, mannitol, sorbitol and lactose as examples of “sugars” that could be used as wetting agents (see Exhibit C, the '505 patent, column 3, lines 16-17).

2. Procedural history of the current litigation

On October 3, 2002, Biovail filed its Amended Complaint alleging TorPharm's infringement of the patents-in-suit. This allegation of infringement is based on the filing of TorPharm's ANDA and 35 U.S.C. § 271(e)(2). The action is premised solely upon TorPharm's submission of an ANDA to the FDA, which is considered a "technical" or "artificial" act of infringement that Congress created to provide patentees a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to resolve any dispute concerning infringement and validity promptly. *Glaxo v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

On October 10, 2002, TorPharm filed its Answer, Affirmative Defenses and Counterclaim (hereinafter "Answer") to Biovail's Amended Complaint. TorPharm answered that the patents-in-suit were not infringed and warned that further defenses or counterclaims of invalidity or for antitrust violations might be forthcoming.

On May 8, 2003, this Court entered an order granting TorPharm leave to file an amended answer and counterclaims alleging invalidity of the patents-in-suit.

On May 9, 2003, TorPharm filed its Amended Answer, Affirmative Defense, and Counterclaim (hereinafter "Amended Answer") including counterclaims and affirmative defenses of invalidity of the asserted patent claims for failure to satisfy the requirements of 35 U.S.C. §§ 102 and 103.

On May 16, 2003, the court set forth a scheduling order that established an initial schedule for claim construction briefing, which set deadlines of May 16, 2003 for TorPharm's opening claim construction brief, June 2, 2003 for Biovail's claim construction brief, and June 6, 2003 for TorPharm's reply thereto.

TorPharm's opening claim construction brief was filed on May 16, 2003.

On June 2, 2003, Biovail filed its claim construction brief indicating that “sugars” are included in the claims, but failing to provide a definition for the term “sugar” or “sugars.” Biovail stated:

Thus, in both claims, “wetting agents” are those classes of compounds that are listed in the Markush groups. **Sugars** are specifically included.

Exhibit D, Biovail's Memorandum of Law on Claim Construction, page 11 (emphasis in original).

Thus, Biovail failed to provide any definition for “sugar” or “sugars.”

On June 6, 2003, TorPharm responded rebutting Biovail's arguments set forth in its claim construction brief.

On October 9, 2003, the current litigation was referred to Magistrate Welsh for a settlement negotiations between the parties.

On October 27, 2003, a settlement conference was set for December 16, 2003. Unfortunately, the settlement conference did not resolve this litigation and the parties then resumed preparation for the *Markman* hearing at which time the court would construe the disputed claim terms.

A series of Orders then ensued which eventually set the *Markman* hearing for June 9, 2004 at 10:00AM. Included in this series of Orders was an Order dated January 21, 2004 which set a pre-*Markman* hearing for February 10, 2004.

The February 10, 2004 pre-*Markman* hearing was conducted to discuss the manner for conducting the *Markman* hearing and other matters. Present at the hearing were Eric Cohen and Robert Tinter for Biovail and Michael Berkowitz, Robert Silver, and Manny Pokotilow for TorPharm. As stated, *supra*, prior to the February 10, 2004 hearing, Biovail indicated that the terms “sugar” and “sugars” are included in the claims of the patents-in-suit but failed to provide any definition for these terms.

During the February 10, 2004 pre-*Markman* hearing there was discussion regarding Biovail's definition of "wetting agents" as that term appears in the claims of the patents-in-suit. On several occasions, Biovail's counsel clearly stated that the terms "sugar" and "sugars" as those terms are used in the claims include all sugars. For example, Biovail's counsel stated:

MR. COHEN: And so, in the [*Markush*] group then, is says, wetting agents selected from the group consisting of sugars. So, wetting agents selected from the group, so sugar by definition, since wetting agent can be selected from the group consisting of sugars, sugar by definition in that construct is a wetting agent. It's got to be, otherwise, why would --

THE COURT: All sugars?

MR. COHEN: All sugars.

Exhibit E, Transcript of February 10, 2004 Proceedings "Transcript" at page 24, lines 10-17. Later in the same proceeding, Biovail's counsel reiterated his position that all sugars were included within the claim term "wetting agent" as follows:

THE COURT: But it's hard for me to believe that you would -- that you would be allowed to say, all sugars. I mean, I have to say it, if -- I may interpret it that way then, down the pike, change -- say that you couldn't be, because -- because it's just too broad.

MR. COHEN: Well, I -- I -- there's nothing -- there's nothing in -- there's no evidence that suggests that with respect to diltiazem, sugars is too broad. That's something -- if -- if it says, sugars then, the federal circuit says, it means just what it says, sugars. There's no limitation anywhere in the specification or in the prosecution history as to what kind of sugars. There's no limitation in the claim.

But the federal circuit says, that you use words like, sugar, you give them their ordinary meaning. You can't -- and for better or for worse -- sugars means sugars.

Exhibit E, Transcript at page 28, line 25 to page 29, line 14. Thus, at the February 10 pre-*Markman* conference, Biovail, for the first time provided a very broad definition of the claim term "sugar" or "sugars" that encompasses all sugars.

Based upon the above statements by Biovail's counsel, TorPharm now seeks to amend its Amended Answer to add affirmative defenses and counterclaims for invalidity of the patent-in-suit for failure to meet the requirements of 35 U.S.C. §§ 102, 103, and 112 due to overbreadth of the claims of the patents-in-suit. TorPharm also seeks to assert affirmative defenses and counterclaims based upon anti-trust violations under 15 U.S.C. § 2.

The date for filing amended pleadings in this case has passed. A copy of this court's December 19, 2002 Scheduling Order setting the deadline for amending the pleadings as April 30, 2003 is attached hereto as Exhibit F. Although the deadline has passed, it is appropriate for this Court to grant TorPharm's motion to amend its pleading to include counts for invalidity and antitrust violations based upon claim overbreadth due to Biovail's all encompassing definition of the term "sugar" or "sugars" recently stated at the February 10, 2004 pre-*Markman* conference.

A. Rule 15 Should be Construed Liberally to Allow TorPharm's Amendment to its Pleadings

Federal Rules of Civil Procedure Rule 15¹ states that leave to amend pleadings "shall be freely given when justice so requires." Accordingly, leave should be granted absent a reason to the contrary, "such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, [and] undue prejudice to the opposing party." *Foman v. Davis*, 371 U.S. 178, 182 (1962) (allowing the amendment of the pleadings even after

¹Rule 15 states, in part:

(a) Amendments. A party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served or, if the pleading is one to which no responsive pleading is permitted and the action has not been placed upon the trial calendar, the party may so amend it at any time within 20 days after it is served. Otherwise a party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires. A party shall plead in response to an amended pleading within the time remaining for response to the original pleading or within 10 days after service of the amended pleading, whichever period may be the longer, unless the court otherwise orders.

judgment had been entered); *Adams v. Gould Inc.*, 739 F.2d 858, 869-870 (3d Cir. 1984) (failure to amend the complaint by the district court was abuse of discretion where the non-movant failed to show bad faith, undue delay, or prejudice and the movant stated a sufficient legal theory as a basis for the amendment.). There must be justification for denying the amendment. *Foman*, 371 U.S. at 182.

The Third Circuit has stated a “general presumption in favor of allowing a party to amend the pleadings.” *Boileau v. Bethlehem Steel Corp.*, 730 F.2d 929, 938 (3d Cir. 1984). The following justifications for denying the entry of an amendment to the pleadings are available to a district court: “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowing the amendment, and futility of granting the amendment.” *Clark v. Commonwealth of Pennsylvania*, 885 F. Supp 694, 705 (E.D. Pa. 1995) (denying entry of amendment as futile), citing *Foman*, 371 U.S. at 182. Of the above listed considerations, “[w]hen considering whether to allow leave to amend, ‘prejudice to the non-moving party is the touchstone for denial of an amendment.’” *Phillips v. Heydt*, 197 F. Supp.2d 207, 225 (E.D. PA. 2002), citing *Cornell & Co. v. Occupational Safety & Health Review Comm’n*, 573 F.2d 820, 823 (3d Cir. 1978). As will be shown, *infra*, Biovail will not be prejudiced by TorPharm’s amending its affirmative defenses and counterclaims. In addition, none of the other *Foman* justifications for denial are present.

B. TorPharm’s Amendment is not Within the Exceptions to Liberal Amendment Under Federal Rule 15.

1. There is no prejudice to Biovail.

Biovail will not be prejudiced by the entry of TorPharm’s Second Amended Answer. To date,

there has been no discovery on the issues of invalidity. The additional counterclaims and affirmative defenses for claim overbreadth arising from Biovail's recent broad definition of the term "sugar" or "sugars" are also invalidity bases for relief. Thus, the addition of these counterclaims and affirmative defenses will not create any additional burden for Biovail. Additionally, TorPharm's proposed antitrust counterclaims and affirmative defenses will not prejudice Biovail in that these rely on previously discovered evidence [and/or the invalidity issues which still require discovery]. Since the additional counterclaims and affirmative defenses will not significantly impact the discovery process, Biovail will not be prejudiced.

Biovail will also not be prejudiced because it was aware of the possibility of antitrust claims and additional invalidity claims as they have been a part of TorPharm's pleadings from the outset. In the initial Answer filed on October 10, 2002, TorPharm answered as follows:

Defendant reserves the right to assert further affirmative defenses and counterclaims, including but not limited to invalidity of the patents in suit, unenforceability of the patents in suit, and for anti-trust violations for the institution of a sham suit

See Exhibit G, Answer at page 5. Additionally, TorPharm's Answer states in Count III of the Counterclaims that "Biovail's claim is an attempt to unduly delay this case and maintain its monopoly power in the marketplace for the product" (See Exhibit G, Answer at page 12). Thus, Biovail has had ample notification that such affirmative defenses and counterclaims were possible. Any argument that Biovail was prejudiced should be disregarded.

2. TorPharm has not engaged in undue delay and is not acting in bad faith.

TorPharm has not engaged in any undue delay and is not acting in bad faith in bringing the present motion to amend its Amended Answer. Although the date for amending pleadings has passed, TorPharm was only recently notified of Biovail's broad definition of the term "sugar" or "sugars" on

February 10, 2004. Following investigation to ensure that the counterclaims and affirmative defenses were viable and not futile, TorPharm filed the present motion. Thus, there was no undue delay or bad faith on TorPharm's part. Additionally, even if delay is found by this Court, "[t]he passage of time, without more, does not require that a motion to amend a complaint be denied ... [t]he question of undue delay ... requires that we focus on [the movant's] motives." *Adams*, 739 F.2d at 868. There is no undue delay here because TorPharm's motion for leave to file the Second Amended Answer was filed soon after TorPharm was notified of Biovail's broad definition of the term "sugar" or "sugars." Thus, there is no undue delay that would prevent the entry of TorPharm's Second Amended Answer.

3. The other *Foman* justifications do not apply.

This is not an attempt to cure recurring deficiencies nor are the affirmative defenses and/or counterclaims futile. TorPharm's Second Amended Answer is not the result of a need to cure deficiencies but, instead, is the result of the newly asserted claim scope by Biovail. The submitted amendment is also not futile in that the overbreadth and antitrust claims have a reasonable basis for being asserted. The asserted breadth for the claim term "sugar" or "sugars" will potentially make the patents-in-suit monopolize a large range of obvious compositions and thereby violate 35 U.S.C. § 103. See *Cosden Oil & Chemical Co. v. American Hoechst Corp.*, 543 F. Supp. 522, 544 (D. Del. 1982). Additionally, claiming excessively broad compositions may run afoul of the fundamental concepts of 35 U.S.C. § 112. See *Vas-Cath Inc. v. Mahurkar*, 745 F. Supp. 517, 530 (N.D. Ill. 1990). Finally, the assertions improperly increasing the breadth of the claim term "sugar" or "sugars" make it more likely that the patents-in-suit are invalid and, thereby, increase the likelihood that the current litigation is a "sham litigation" in violation of 15 U.S.C. § 2. Thus, the current amendment submitted by TorPharm should not be deemed futile.

C. Biovail's Recent Assertions Before this Court Provide "Good Cause" to Allow Amendment of the Pleadings Under Rule 16.

Federal Rule of Civil Procedure Rule 16 governs the use of scheduling orders and allows for the amendment of pleadings after the deadline for amendment has past where good cause has been shown. Rule 16 states, in part:

(b) Scheduling and Planning. Except in categories of actions exempted by district court rule as inappropriate, the district judge, or a magistrate judge when authorized by district court rule, shall, after receiving the report from the parties under Rule 26(f) or after consulting with the attorneys for the parties and any unrepresented parties by a scheduling conference, telephone, mail, or other suitable means, enter a scheduling order that limits the time ... to amend the pleadings A schedule shall not be modified except upon a showing of good cause and by leave of the district judge or, when authorized by local rule, by a magistrate judge.

Fed. Rules, Civ. Proc. Rule 16.

TorPharm has been diligent in the filing of the current amendment in that the bases for the affirmative defenses and counterclaims in TorPharm's Second Amended Answer were not known until February 10, 2004. See *Eastern Minerals & Chemical Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000) (denying motion to amend due to lack of diligence on the part of the moving party). Additionally, in the context of pretrial case management, the discretion of the district court is broad. See generally *Adams*, 739 F.2d at 868. Thus, TorPharm requests that leave to amend be granted under Rule 16.

D. Conclusion

For the foregoing reasons, TorPharm's motion for leave to file its Second Amended Answer should be GRANTED.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

July 13, 2004

By 

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